

REMARKS

I. Support for the Amendments

Claims 1-21 were originally in the application. Claims 6-21 were canceled previously without prejudice or disclaimer of any subject matter. Claims 1-5 and 22 were previously in the application.

Claims 1, 2, 4, 5 and 22 are presently in the application. Claims 1, 2, 4, and 22 have been amended, and claim 3 has been canceled without prejudice. No new matter has been added by virtue of these amendments.

Support for amended claims 1, 2, 4, and 22 can be found in the original specification and claims. The amendment to claim 4 is technical. Claim 4, which was previously dependent on canceled claim 3, is now dependent on claim 1.

Additional support for amended claims 1 and 22 can be found, e.g., on page 3, lines 2-22; on page 4, lines 1-4; on page 5, line 25; on page 6, lines 1-7; on page 7, lines 4-10 and 24-25; from page 8, line 25, to page 11, line 4; from page 12, line 10, to page 13, line 2; on page 13, lines 11-18; and in the Examples, particularly in Examples 1-3, and Figures. Additional support for amended claim 2 can be found, e.g., on page 3, lines 2-22; on page 7, lines 4-10 and 24-25; from page 8, line 25, to page 11, line 4; from page 12, line 10, to page 13, line 2; and in the Examples.

II. Status of the Claims

Claims 1-21 were originally in the application. Claims 1-21 were subject to an election/restriction requirement, and claims 1-5 were elected with traverse. Claims 6-21 were

canceled without prejudice or disclaimer of any subject matter. Claims 1-5 and 22 were previously in the application.

Claims 1, 2, 4, 5 and 22 are presently in the application. Claims 1, 2, 4, and 22 have been amended, and claim 3 has been canceled without prejudice. No new matter has been added.

III. The Information Disclosure Statement is Acknowledged

Applicants thank the Examiner for acknowledging the Information Disclosure Statement, mailed on November 24, 2004, and the references cited therein.

IV. The Objection to Claim 1 is Accommodated

The Examiner has objected to claim 1. Applicants respectfully submit that the amendments to claim 1 have accommodated the Examiner's rejected.

V. Rejection of Claims 1-5 and 22 Under 35 U.S.C. §112, First Paragraph, with Respect to the Written Description, is Traversed, but Accommodated in Part and Rendered Moot in Part

The Examiner has rejected claims 1-5 and 22 under 35 U.S.C. §112, first paragraph, "as failing to comply with the written description requirement." Applicants respectfully traverse the Examiner's rejection.

The Patent Office alleges:

The limitation of "a non-human TCR specific for a tumor-associated antigen (TAA) and restricted by HLA" as newly amended in the preamble of claim 1 does not

have support on pg 3, lines 8-18....While the specification contemplates obtaining TCRs from any non-human vertebrate restricted by human HLA, the specification does not contemplate obtaining non-human TCR restricted by any HLA as broadly claimed....[Pp. 2-3.]

Applicants respectfully traverse the rejection, including the remarks related to support of the preamble, but have amended the preamble of claim 1 in the interest of speeding prosecution, both with respect to the Examiner's remarks under §112, first paragraph, and with respect to the Examiner's remarks under §112, second paragraph.

Applicants thank the Examiner for withdrawing the remaining portions of the rejection. As noted, claims 2, 4, 5, and 22 are dependent on claim 1. The rejection is moot with respect to claim 3, which has been canceled without prejudice.

Applicants respectfully submit that claim 1 fulfills the requirements of 35 U.S.C. §112, first paragraph, with respect to the written description requirement, and that claims 1, 2, 4, 5, and 22 are in a condition for allowance.

VI. Rejection of Claims 1-5 and 22 Under 35 U.S.C. §112, First Paragraph, with Respect to Enablement, is Accommodated in Part and Rendered Moot in Part

The Examiner has rejected claims 1-5 and 22 under 35 U.S.C. §112, first paragraph with respect to the enablement requirement.

The Patent Office alleges:

Claims 1-5 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for obtaining mouse TCRs and immunizing transgenic mice that express human HLA molecules, does not reasonably provide enablement of obtaining any species of TCR other than mouse or immunizing any transgenic non-human mammal species having human HLA as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for reasons of record.

The enablement rejection regarding the breadth of obtaining any species of TCR and immunizing any non-human transgenic species having human HLA of record (4-10-01) is maintained for reasons of record. The enablement rejection was overcome on 10-15-01, when applicants limited the claims to obtaining the α and β chains of a mouse TCR and immunizing a transgenic mouse. However, the amendment filed 7-1-02 deleted the limitation of obtaining a mouse TCR and reintroduced the breadth of immunizing any "transgenic non-human mammal species" without marking the change to the claim. In view of the amendment filed 7-1-02 and the current amendment filed 9-24-04 which encompass obtaining any species of TCR and immunizing any transgenic non-human mammal that has human HLA, the enablement rejection regarding the breadth of obtaining any species of TCR and immunizing any non-human transgenic specie of record is hereby revived. The basis of the rejection can be found in the office action of 4-10-01 on pg 5 and 6 (and previous office actions). [Pp. 4-5; emphasis in original.]

Applicants respectfully submit that the deletion of the limitation was inadvertent.

Applicants have reintroduced the limitation accordingly.

Applicants respectfully submit that claims 1, 2, 4, 5, and 22 fulfill the requirements of 35 U.S.C. §112, first paragraph, with respect to the enablement requirement, and that claims 1, 2, 4, 5, and 22 are in a condition for allowance.

VII. Rejection of Claims 1-5 and 22 Under 35 U.S.C. §112, Second Paragraph, is Traversed, but Accommodated

The Examiner has rejected claims 1-5 and 22 under 35 U.S.C. §112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Applicants respectfully traverse the Examiner's rejection.

The Patent Office alleges:

The preamble of claim 1 as newly amended is indefinite because it is not commensurate in scope of the body of the claim. The preamble requires the production

of a nucleic acid fusion molecule while step e results in producing a nucleic acid sequence encoding a single-chain TCR comprising a variable region of an α TCR and a variable region of a β TCR. The preamble should reflect the fact that the claim is limited to the production of a nucleic acid sequence encoding a single-chain TCR as in the body of the claim.

The preamble of claim 1 as newly amended is indefinite. TCR α and TCR β chains are narrower in scope with any non-human TCR specific for TAA. Therefore, any non-human TCR that is specific for TAA as broadly claimed does not further limit the TCR α and TCR β chains. It is unclear if the TCR fusion protein as a whole is specific for TAA or if both the variable TCR α chain and the variable TCR β chain are specific for TAA.

Claim 1, step a, as newly amended is indefinite. It is unclear if the CLT has i) a TCR comprising a TCR α chain and a TCR β chain, wherein said TCR is specific for said TAA or ii) a TCR comprising a TCR α chain that is specific for said TAA and a TCR β chain that is specific for said TAA.

Claim 1, step e, is indefinite in view of the preamble as newly amended. It is unclear whether the single-chain fusion protein as a whole is specific for said TAA or if both the variable TCR α and the variable TCR β chain used to make the single chain fusion protein are specific for TAA.

Claim 22 as newly amended is indefinite. The metes and bounds of single chain TCR comprising a TCR “derivative that retains the HLA restriction and TAA-specificity characteristics of the TCR of step a)” cannot be determined. It is unclear if the single chain must have an α and a β chain, each of which are human HLA restricted and TAA-specific (a narrower scope) or if the claim is meant to encompass any single chain that is human HLA restricted and TAA-specific (a broader scope). [Pp. 5-6; emphasis in original.]

Applicants respectfully traverse these rejections. For reasons not related to patentability, however, Applicants have amended claims 1 and 22. Claims 2, 4, and 5 are dependent on claim 1.

Applicants thank the Examiner for withdrawing the previous indefiniteness rejections.

Applicants respectfully submit that claims 1, 2, 4, 5, and 22 fulfill the requirements of 35 U.S.C. §112, second paragraph, and that claims 1, 2, 4, 5, and 22 are in a condition for allowance.

CONCLUSION

It is believed that all outstanding rejections have been addressed by this submission and that all the claims are in condition for allowance. If discussion of any amendment or remark made herein would advance this important case to allowance, the Examiner is invited to call the undersigned as soon as convenient.

In view of the foregoing amendments and remarks, the present application is respectfully considered in condition for allowance. An early reconsideration and notice of allowance are earnestly solicited.

Applicants believe that no extension of time is required and that no additional fee is due.
If, however, a petition for an extension of time is required, then the Examiner is requested to treat this as a conditional petition for an extension of time. Although it is not believed that any fee is required, in addition to the fee submitted herewith, to consider this submission, the Commissioner is hereby authorized to charge our deposit account no. 04-1105 should any fee be deemed necessary.

Respectfully submitted,

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